Philogen
innovating targeting

PRESS RELEASE

PHILOGEN S.p.A. (Courtesy English Translation)

THE BOARD OF DIRECTORS APPROVES THE NET FINANCIAL POSITION FOR THE THIRD QUARTER OF 2024, WHICH IS POSITIVE AND AMOUNTS TO 42,964 THOUSAND EUROS, AND NOTES THE PROGRESS OF THE MAIN TRIALS *NIDLEGY*™ AND FIBROMUN IN LINE WITH EXPECTED TIMELINES AND THE DEVELOPMENT OF OTHER INDUSTRIAL ACTIVITIES

IN THE SAME MEETING, THE BOARD OF DIRECTORS HAS, INTER ALIA:

- **approved the Regulation for the 2027-2029 Stock Grant Plan and the Regulation for the 2024-2026 Director Stock Ownership Plan;**
- **implemented the 2024-2026 Stock Grant Plan, the 2027-2029 Stock Grant Plan and the 2024-2026 Director Stock Ownership Plan.**

Siena (Italy), Nov. 7 2024 – In compliance with the disclosure commitments made by the Company as part of the listing process, the Company announces that the Board of Directors of Philogen S.p.A. (the "**Company**" or "**Philogen**" and, together with its Swiss subsidiary Philochem, the "**Group**"), which met today, approved the Group's net financial position as of Sept. 30, 2024, and noted the progress of the main trials *Nidlegy*™ and Fibromun, as well as the positive development of other industrial activities.

Dario Neri, CEO and Chief Scientific Officer of Philogen S.p.A., commented:

"We are pleased with the progress achieved with both our biological and chemical experimental drugs. The Nidlegy™ programme for the treatment of melanoma is currently under review by the European Medicines Agency after completion of the Phase III clinical trial. The Fibromun study in soft tissue sarcoma has reached enrolment of 118 patients as per the protocol and we are awaiting the occurrence of the necessary events (e.g. disease progression) for the completion of the study, which is expected in late 2024/early 2025.

The commercial agreements with Sun Pharma, which were announced to the market in 2023 and 2024 concerning, respectively, Nidlegy™ and Fibromun, will reduce the need to invest in an extensive internal sales structure, and will provide Philogen with net sales of approximately 50% and 45%, respectively.

Our research centre in Zurich recently identified a new small chemical molecule specific for a target expressed by prostate cancer (ACP-3). This new ligand, named OncoACP-3, has shown the ability to localise extremely selectively and efficiently in prostate tumours, while sparing healthy organs. Based on the targeting profiles observed, ACP-3 has the potential to overcome certain limitations (both diagnostic and therapeutic) associated with drugs used to treat prostate cancer patients that are directed against targets (e.g., PSMA) which are less selective than ACP-3.

The development of ongoing scientific projects and collaborations are considerably strengthening the Group's financial position in the year 2024. It is expected that, at the end of the financial year 2024, revenues will be approximately three times those of the previous year (Euro 25 million in 2023), and the net financial position will also be positively affected. The strong financial position will further support the Group's structure and will allow for investments in clinical trials to be increased, and production capacity to be expanded to include small organic molecules as well as biologic drugs."

NET FINANCIAL POSITION AS OF SEPTEMBER 30, 2024

The following is a table of the Philogen Group's Net Financial Debt as of September 30, 2023, prepared in accordance with ESMA Guideline 32-382-1138 of March 4, 2021 and Consob's Attention Call No. 5/21:

Figures in thousands of euros **Net financial debt**	**September 30, 2024**	**June 30, 2024**	**March 31, 2024**	**December 31, 2023**
(A) Cash on hand	4.647	12.264	6.960	10.635
(B) Equivalents to cash on hand	-	-	5.000	5.000
(C) Other current financial assets	52.259	52.345	57.040	59.709
(D) Liquidity (A+B+C)	**56.906**	**64.609**	**69.000**	**75.344**
(E) Current financial debt	28	74	60	22
(F) Current part of non-current financial debt	1.923	1.884	1.865	1.868
(G) Net current financial debt (E+F)	**1.950**	**1.958**	**1.925**	**1.890**
(H) NET CURRENT FINANCIAL DEBT (G-D)	**(54.956)**	**(62.651)**	**(67.075)**	**(73.455)**
(I) Non-current financial debt	11.992	11.955	12.327	13.025
(J) Debt instruments	-	-	-	-
(K) Trade and other current payables	-	-	-	-
(L) Non-current financial debt (I+J+K)	**11.992**	**11.955**	**12.327**	**13.025**
(M) NET FINANCIAL DEBT (H+L)	**(42.964)**	**(50.696)**	**(54.748)**	**(60.430)**

(*) Net financial debt is an alternative performance indicator, not identified as an accounting measure under IFRS, and therefore, should not be considered an alternative measure to those provided by the Group's financial statements for assessing the Group's financial position.

The Group ended the third quarter of 2024 with a positive net financial position of 42,964 thousand euros compared to a positive net financial position of 50,699 thousand euros as of June 30, 2024, showing a percentage decrease of 15.3%.

As of September 30, 2024, the Group closes with liquidity of 56,906 thousand euros compared to liquidity of 64,609 thousand euros as of June 30, 2024, showing a decrease of 11.9%. This decrease, mitigated by the positive contribution of financial management of approximately 408 thousand euros, is mainly attributable to (i) costs from ordinary operations of approximately 6,910 thousand euros (ii) investments in new machinery, equipment and specific plants of approximately 956 thousand euros, (iii) payment of the instalment of a loan for 245 thousand euros. However, it should be noted that as of 30 September, the Group had a net balance of short-term credit and debit positions of about 60,000 thousand euros, which will contribute, by the end of the year, to significantly increase the Group's liquidity.

Current and non-current financial indebtedness increased from 13,913 thousand euros at 30 June 2024 to 13,942 thousand euros at 30 September 2024, thus remaining substantially unchanged, as the reduction related to the progress of existing amortisation schedules was offset by Istat increases applied to rents. Financial indebtedness is mainly represented by (i) the debt inherent to the leases of the three corporate sites (IFRS 16) of approximately 11,752 thousand euros, and (ii) the medium-long term loan for 2,162 thousand euros agreed with the Banca Intesa Group (formerly Ubi Banca S.p.A.) in January 2021 to partially finance the construction and equipment of the new GMP plant at the Rosia (Siena) site.

UPDATE ON THE GROUP'S INDUSTRIAL PROGRAMS

The status of the various industrial programmes can be summarised as follows:

- Nidlegy™ - biopharmaceutical product designed for the treatment of skin cancer

The European Medicines Agency is currently reviewing the Marketing Authorisation Application submission for melanoma.

The review process of the full dossier by the regulatory authorities is expected in the summer of 2025.

Patient enrolment in the US Phase III study in Stage IIIB/C melanoma continues in line with company expectations. To date, 105 patients of the 186 foreseen by the protocol have been enrolled, and 33 clinical centres have been opened.

Two Phase II studies are ongoing in '*High-Risk Locally Advanced*' Basal Cell Carcinoma (BCC) and other non-melanoma skin cancers. The Group accelerated activities in BCC, based on the high rate of durable complete remissions (clinical and/or pathological CR) observed in patients treated with Nidlegy™. To date, 91 patients have been enrolled in the ongoing Duncan study in Switzerland, Poland and Germany. Discussions are ongoing to finalise an industrial development plan to take the drug to registration. The two clinical trials also allow Nidlegy™ to be investigated in other non-melanoma skin cancers (e.g. squamous cell carcinoma, Merkel Cell Carcinoma).

- Fibromun - biopharmaceutical product designed for the treatment of soft tissue sarcoma (STS) and Glioblastoma

In the European Phase III study in first-line STS, in combination with doxorubicin, all 118 patients foreseen by the protocol have been enrolled. The study was conducted in Germany, Italy, Spain, Poland and France. Patients are randomised 1:1. 50% of patients are treated with doxorubicin (control arm) and the other 50% are treated with doxorubicin in combination with Fibromun (experimental arm). The study, whose primary endpoint is Progression Free Survival (PFS), was designed to observe an improvement of at least 80% in the experimental arm versus the control arm. Based on historical data, the median PFS of doxorubicin alone is expected to be around 4.6 months.

The US Phase IIb study in first-line leiomyosarcoma in combination with doxorubicin is ongoing at 7 clinical centres in the US. It should be noted that leiomyosarcoma is the most common subtype of STS.

The randomised phase of the European Phase II trial in third-line STS in combination with dacarbazine continued. The trial enrolled 88 patients out of a planned 92 patients.

With regard to the Phase I/II study in second-line Glioblastoma in combination with lomustine, Phase I is completed with 15 patients divided into 3 cohorts and Phase II is ongoing. To date, 111 of the 158 patients in the Phase II study have been enrolled. The study is currently ongoing in Switzerland, Italy and Germany. Philogen is working with the aim of opening further centres in major European countries.

A new Phase II study in pre-treated Glioblastoma in combination with lomustine started in 2023. The protocol envisages the enrolment of up to 90 patients. 14 patients have already been included in the study.

The Phase I/II/IIb trial in first-line Glioblastoma in combination with radiotherapy and temozolomide continues at the University Hospital of Zurich. The last of the five cohorts in the Phase I trial is currently underway.

- OncoFAP - small organic molecule with high affinity for Fibroblast Activation Protein (FAP). FAP is highly expressed in over 90% of epithelial tumours. The Company is currently developing several pharmaceutical derivatives based on the OncoFAP ligand.

The radio-diagnostic derivative 68Ga-OncoFAP has completed a Phase I clinical trial in patients with solid tumours. Blue Earth Diagnostics (Bracco), to whom the product was licensed, is planning the Phase II study.

The Company-sponsored clinical study of the radiotherapeutic derivative 177Lu-OncoFAP-23 is scheduled to start in 2024. The study has been approved by the relevant authorities and the first patients are scheduled to start in early 2025.

Experimental data obtained in several preclinical models with OncoFAP-GlyPro-MMAE (a non-radioactive derivative of OncoFAP conjugated to cytotoxic drugs) has shown an excellent ability to block the growth of several tumour types. To date, the drug is the subject of a clinical trial in dogs suffering from spontaneous neoplasia at the University of Milan. The results observed so far are excellent. The start of GMP production of OncoFAP-GlyPro-MMAE, preparatory to clinical trials in human patients, is also planned.

- OncoACP-3 e OncoCAIX - small organic molecules with high affinity for, respectively, Acid Phosphatase 3 (ACP-3) and carbonic anhydrase IX (CAIX), two markers for prostate and kidney cancer.

Two Company-sponsored clinical studies of the 68Ga-OncoACP-3 and 68Ga-OncoCAIX derivatives (diagnostic derivatives) are scheduled to start in 2024. Submissions of the studies to the relevant regulatory authorities have already been made.

68Ga-OncoACP-3 has been requested by some clinical centres for compassionate purposes. Initial imaging data obtained in prostate cancer patients confirmed excellent tumour-targeting properties of the molecule, clearly superior to drugs commonly used on the market today (ligands against PSMA).

- Products in *partnerships*

Partnerships continued on (i) Dekavil (Pfizer) and (ii) small organic molecules (Janssen and Bracco) and (iii) Nidlegy™ (Sun Pharma and MSD).

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The director in charge of preparing corporate accounting documents, Laura Baldi, declares pursuant to paragraph 2 Article 154 bis of the Consolidated Law on Finance that the accounting information contained in this press release corresponds to the documentary results, books and accounting records.

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OTHER SIGNIFICANT BOARD RESOLUTIONS

With reference to the Stock Grant Plan 2027-2029, reserved for the Group's employees and consultants, and the 'Directors' Stock Ownership Plan 2024-2026', reserved for the Company's executive directors, approved by the Company's Shareholders' Meeting on 29 April 2024, the Board of Directors, upon the proposal of the Appointments and Remuneration Committee, approved the respective regulations of the Plans.

Furthermore, the Board of Directors, having heard the opinion of the Appointments and Remuneration Committee, implemented the three existing share-based compensation plans.

In particular:

- with reference to the Stock Grant Plan 2024-2026, reserved to the Group's employees, the Board of Directors, following the end of the three-year performance period, ascertained, for the beneficiaries identified for the 1st Cycle of the Plan, the partial achievement of the objectives for the three-year period 2021-2024 and the existence of all the circumstances on which the assignment of the shares was conditional; consequently, against no. 145,000 units allocated under the 1st Cycle of the Plan, the Board of Directors resolved to assign a total of 46,940 ordinary shares of the Company through the use of shares already at Philogen's disposal;

- with reference to the 2027-2029 Stock Grant Plan, reserved for the Group's employees and consultants, the Board of Directors identified the beneficiaries and assigned them, free of charge, a total of 118,000 units for the 1st Cycle of the Plan;

- with reference to the 2024-2026 Directors' Stock Ownership Plan, reserved for the Company's executive directors, the Board of Directors identified the beneficiaries and assigned a total of 600,000 units to them free of charge.

The features of the 2024-2026 Stock Grant Plan, the 2027-2029 Stock Grant Plan and the 2024-2026 Director Stock Ownership Plan are set out in the respective disclosure documents available to the public at the Company's registered office, on the Company's website www.philogen.com (Section 'Governance/Incentive Plans') and on the authorised storage mechanism called '1Info' (www.1info.it).

The information set forth in Annex 3A, Schedule 7, of the Issuers' Regulation adopted by Consob with resolution No. 11971/99 and subsequent amendments, and table No. 1 set forth therein in paragraph 4.24, will be provided, pursuant to Article 84-bis, paragraph 5, of

the Issuers' Regulation, by the date of publication of the remuneration report pursuant to Article 123-ter of the Consolidated Law on Finance.

Philogen Group Description.

Philogen is an Italian-Swiss company active in the biotechnology sector, specializing in the research and development of pharmaceuticals for the treatment of highly lethal diseases. The Group mainly discovers and develops targeted anticancer drugs by exploiting high-affinity ligands for tumor markers (also called tumor antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using Antibody Phage Display Libraries and DNA-Encoded Chemical Libraries technologies.

The Group's main therapeutic strategy for the treatment of such diseases is the so-called tumor targeting. This approach is based on the use of ligands capable of selectively delivering very potent therapeutic active ingredients (such as, for example, pro-inflammatory cytokines) at the tumor mass, sparing healthy tissues. Over the years, Philogen has mainly developed monoclonal antibody-based ligands that are specific for antigens expressed in tumor-associated blood vessels but not expressed in blood vessels associated with healthy tissues. These antigens are usually more abundant and more stable than those expressed directly on the surface of tumor cells. This approach, so-called vascular targeting, is used for most of the projects pursued by the Group.

The Group's goal is to generate, develop, and commercialize innovative products for the treatment of diseases for which medical science has not yet identified satisfactory therapies. This is achieved by leveraging (i) proprietary technologies for the isolation of ligands that react with antigens present in specific diseases, (ii) experience in developing products targeted to the tissues affected by the disease, (iii) experience in drug manufacturing and development, and (iv) the Group's extensive portfolio of patents and intellectual property rights.

Although the Group's drugs are primarily oncology applications, the targeting approach is also potentially applicable to other diseases, such as some chronic inflammatory diseases.

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FOR MORE INFORMATION:

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